Alabama Medicaid DUR Board Meeting Minutes
January 26, 2011

Members Present: Paula Thompson, Donald Marks, Kevin Royal, Kelli Littlejohn, Bernie Olin, Dan McConaghy, Jimmy Jackson, Denise Thornley-Brown, Robert Moon, David Harwood, Daniel Mims

Also Present: Clemice Hurst, Tiffany Minnifield, Christina Faulkner, Pam Parker-AU pharmacy student

Members Absent: Kevin Green, Rhonda Harden, Hugh Frazer

Call to Order: Paula Thompson, Vice-Chair filled in for Chair, Kevin Green. Paula called the meeting to order at 1:00p.m.

Review and Adoption of Minutes of October 27, 2010 meeting: Regarding the October 27, 2010 DUR Board minutes, Paula Thompson requested that the minutes be amended to reflect a 66.13% approval rate for the Monthly Manual Prior Authorization and Overrides report for the Month of June 2010. Paula asked if there were any further changes to the minutes. Paula asked for a voice vote to approve the minutes as amended. Bernie Olin made a motion. The motion was seconded by Donald Marks. A voice vote to approve the minutes as amended was unanimous.

Kelli Littlejohn introduced the new Medicaid Commissioner, R. Bob Mullins, Jr., M.D., who briefly addressed the DUR Board.

Prior Authorization and Overrides Update: Christina Faulkner began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of September, 2010. She reported 9,606 total requests and an approval rate of 63.54%. She reported 14,262 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for September 2010 she reported that approximately 85% of all manual PAs were responded to in less than two hours, more than 89% in less than four hours and more than 91% in less than eight hours. For the month of October, Christina reported 10,190 manual PA requests and 20,553 electronic PA requests. She reported that more than 74% of PAs were responded to in less than two hours, approximately 89% in less than four hours and approximately 91% in less than eight hours. For the month of November, Christina reported 8,887 manual PA requests and 16,052 electronic PA requests for the same time frame. For November, Christina reported between 79 and 80% approved in less than two hours, approximately 89% in less than four hours and between 90 and 91% approved in less than eight hours.

Program Summary Review: Christina briefly reviewed the Alabama Medicaid Program Summary on page 24. From the Six Month Assessment, she noted approximately 4.2 million prescriptions and an average paid per prescription of $60.16. Discussion included the implementation of the pharmacy reimbursement Average Acquisition Cost (AAC) modification. Christina then reported the Pre- AAC and Post- AAC Implementation data on page 25.

Cost Management Analysis: Christina reported for October 2008 an average cost per claim of $65.18 and for September 2010 an average cost per claim of $59.28. From the Drug Analysis 3rd Quarter 2010, Christina reported 73.77% generic utilization, 16.42% brand single-source, 3.55% brand multi-source and 6.27% OTC and "other". From the Top 25 Drugs Based on Total Claims from 10/01/2010 – 10/31/2010, Christina reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, Singulair®, azithromycin and alprazolam. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2010 – 10/31/2010: Singulair, Abilify®, Synagis®, Seroquel® and Vyvanse®.

UPDATES

Top 5 Drugs Off-label usage: At the October 2010 DUR meeting, the Board requested that HID estimate off-label usage of the top 5 drugs on the Top 25 Drugs by Claims Cost Report (ie, the number of patients taking the drug with no FDA approved indication/diagnosis found in their claims history). For the month of October 2010, the top 5 drugs were Singulair, Abilify, Synagis, Seroquel and Vyvanse. Because there is a prior authorization in place for Synagis, and one of the requirements is an appropriate diagnosis, Concerta was the next drug in line to be analyzed. Christina reported 33.3% of prescriptions for Singulair lacked an appropriate diagnosis on file, 34.3% for Abilify, 56.8% for Seroquel, 18.0% for Vyvanse and 21.6% for Concerta. She reviewed the list of appropriate diagnoses for each drug. From the Top 15 Therapeutic Classes by Total Cost of Claims from 10/01/2010 – 10/31/2010, Christina reported the top five classes: antipsychotic agents, hemostatics, beta-adrenergic agonists, leukotriene modifiers and amphetamines.

Anti-convulsants, Miscellaneous AHFS Class 281292: In July 2010, the Miscellaneous Anticonvulsant class was the third leading drug class based on claims cost. There were 23,058 prescriptions reported at a cost of $1,900,969, approximately $82 per paid prescription. The DUR Board requested information about the number of patients using anticonvulsants for diagnoses other than epilepsy. Christina reported that in the month of July 2010, there were 17,393 unique recipients using drugs in this AHFS class and that 12,984 of those patients did not have an epilepsy diagnosis on file. Christina explained that the data does not allow relating a diagnosis to a particular drug. She reported the top recurring diagnoses for those patients without an epilepsy diagnosis as: schizoaffective disorder, unspecified hypertension, diabetes mellitus without mention of complication, paranoid type schizophrenia, long term use of other medications, lumbago, unspecified schizophrenia, benign hypertension and unspecified examination. The Board also requested that HID more closely review the Anticonvulsants, Miscellaneous class and determine the unique number of recipients for each drug. There are 17,660 patients taking drugs in this class that do not have a diagnosis of epilepsy or convulsions. Christina reviewed this information from the table on pages 35 and 36 of the DUR Meeting manual. The Board requested that HID provide information at the next DUR meeting on common unlabeled indications for these drugs.

Aripiprazole: At the July DUR meeting, the Board requested information about the number of patients using aripiprazole for treatment of depression rather than for its other indications. Christina informed the Board that there were 38,069 prescriptions for aripiprazole and 7,170 unique recipients in the time frame 08/21/09 to 08/20/10. During that time frame there were 2,217 patients with a diagnosis of depression but no diagnosis of bipolar or schizophrenia on file, and 517 of those were unique recipients. For the same time frame, there were 8,633 patients with no FDA approved diagnosis on file – depression, bipolar, schizophrenia or autism, and 1,709 of those were unique recipients. For Quetiapine XR, during the same time frame, there were 7,573 prescriptions, a total paid of $2,499,852 and 1,853 unique recipients. For patients with a diagnosis of depression but no diagnosis of bipolar or schizophrenia on file, there were 560 prescriptions and 164 unique recipients. There were 1,571 prescriptions for patients with no FDA approved diagnosis on file – depression, bipolar or schizophrenia, which represents 410 unique recipients.

Low Dose Quetiapine: The Board requested information about the number of patients using low-dose quetiapine for treatment of insomnia. Christina reported 12,763 prescriptions for Quetiapine in the time frame 08/21/09 to 08/20/10 at a cost of $1,776,033, for 3,002 unique recipients. During that time frame, she reported 1,145 unique recipients under the age of 18; 1,544 unique recipients without a bipolar or schizophrenia diagnosis; 1,526 unique recipients without a bipolar or dementia diagnosis and 23 unique recipients with an injectable antipsychotic on file. The Board requested that HID develop criteria for low dose Seroquel for patients on injectable antipsychotics.

Top 200 Products in the US Market by Sales: From the table on pages 40 and 41 of the DUR manual, Christina reviewed the top 200 products by sales and by number of prescriptions in the US market.

Methadone: At the October DUR meeting, the Board requested and update regarding methadone utilization. Christina directed the Board to the utilization data on page 42 of the DUR manual. For the time period 04/01/10 to

09/30/10, Christina reported 803 unique recipients; 2,877 prescriptions and a cost of $51,846. She then reviewed the Top 25 Diagnoses for Patients Taking Methadone from page 43 of the manual. Christina then presented the Risk Evaluation and Mitigation Strategies.

Controlled Substance Use: Christina briefly presented the Overview of Controlled Substance Use. She presented a table, found on page 46 of the DUR manual, containing the Top 25 Prescribers for AHFS classes 280808, 281208 and 282408 from 04/01/10 to 09/30/10. She also briefly reviewed the agents within those classes. The Board requested that HID send letters to the top 25 providers.

Intervention Activity: Christina reported for October 2010, 576 profiles reviewed, 493 letters sent and 95 responses received as of the print date of the DUR manual. She further reported the breakdown of all responses and that 42 of 63 physicians indicated that they found the RDUR letters "useful" or "extremely useful". The criteria for the intervention were drug/disease interaction, drug/drug conflicts, over-utilization, and possible non-compliance.

Proposed Criteria: Christina presented the proposed set of 25 criteria to the Board. Tiffany instructed the Board members to mark their ballots. Of the 25 criteria, results from the criteria vote returned 23 approved, 0 rejected, and 2 criteria approved as amended (#11 and #24).

Medicaid Update: Tiffany Minnifield called the board members' attention to their Medicaid packets and reminded them to turn in their vouchers and criteria ballots. Tiffany also informed the group that changes to the update schedule of AAC pricing had been modified allowing providers to receive updates quicker. She also reminded the group that another round of pricing surveys is scheduled to be sent out. Tiffany also reminded the Board that providers must now include the new Medicaid recipient ID numbers when submitting claims. Claims submitted with old Medicaid ID numbers will be rejected. Tiffany then reviewed the updated pharmacy reimbursement for Tdap and Pneumococcal vaccine administration.

P & T Committee Update: Clemice Hurst began the P&T Update by informing the Board that at the last meeting on November 10, the Committee reviewed the Antihypertensive Agents and the Cardiac Agents. She stated that the next P&T meeting will be held on February 9. At the February meeting the committee will review the Respiratory Agents, EENT Preparations and Victoza®.

New Business: Paula Thompson, Vice-chair, asked the Board if there was any new business. There being no new business brought before the Board, Paula Thompson asked for a motion to adjourn. Kevin Royal made a motion to adjourn the meeting. The motion was seconded by Denyse Thornley-Brown. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:30p.m.

Next Meeting Date: The next DUR Board meeting will be held on April 27, 2011.

Respectfully submitted,

Christina Faulkner, PharmD

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
1. Oleptro / Overutilization Alert Message: Oleptro (trazodone extended-release) may be over-utilized. The manufacturer's recommended maximum dose is 375 mg per day. Conflict Code: ER – Overutilization Drugs/Diseases Util A: Oleptro Util B: Util C: Max Dose: 375 mg/day References: Facts & Comparisons, 2010 Updates. Oleptro Prescribing Information, June 2010, Labopharm Pharmaceuticals.	X		
2. Oleptro / Nonadherence Alert Message: Nonadherence may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical costs. Conflict Code: LR – Nonadherence Drugs/Diseases Util A: Oleptro Util B: Util C (Negating): References: Facts & Comparisons, 2010 Updates. Oleptro Prescribing Information, June 2010, Labopharm Pharmaceuticals.	X		
3. Trazodone / Carbamazepine Alert Message: The concurrent use of trazodone-containing products with carbamazepine, a CYP3A4 inducer, may result in significantly reduced trazodone serum concentrations. Trazodone dose adjustment may be required. Conflict Code: ER - Overutilization Drugs/Diseases Util A: Trazodone-All Util B: Carbamazepine Util C: References: Facts & Comparisons, 2010 Updates. Oleptro Prescribing Information, June 2010, Labopharm Pharmaceuticals. Clinical Pharmacology, 2010 Gold Standard Media.	X		

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

4. Trazodone / Phenytoin X

Alert Message: The concurrent use of trazodone-containing products with phenytoin, a CYP3A4 inducer, may result in reduced trazodone serum concentrations as well as increased phenytoin concentrations. Monitor serum levels and adjust dosages as needed.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Trazodone-All	Phenytoin	

References:
Facts & Comparisons, 2010 Updates.
Oleptro Prescribing Information, June 2010, Labopharm Pharmaceuticals.
Clinical Pharmacology, 2010 Gold Standard Media.

5. Trazodone / CYP3A4 Inhibitors X

Alert Message: The concurrent use of trazodone-containing products with CYP3A4 inhibitors may lead to substantial increases in trazodone plasma concentrations with the potential for adverse effects. If trazodone is used with a potent CYP3A4 inhibitor, the risk of cardia arrhythmia may be increased and a lower dose of trazodone should be considered.

Conflict Code: DD – Drug/Drug interaction
Drugs/Diseases

Util A	Util B	Util C
Trazodone – All	Ketoconazole	Clarithromycin
	Itraconazole	Telithromycin
	Fluconazole	Erythromycin
	Voriconazole	Verapamil
	Ritonavir	Diltiazem
	Saquinavir	Nefazodone
	Indinavir	
	Nelfinavir	
	Atazanavir	

References:
Facts & Comparisons, 2010 Updates.
Oleptro Prescribing Information, June 2010, Labopharm Pharmaceuticals.
Clinical Pharmacology, 2010 Gold Standard Media.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

6. Saquinavir / Ritonavir ___X___ _____ _____

Alert Message: The concurrent use of saquinavir (Invirase) and ritonavir (Norvir) may cause prolongation of the QT and PR intervals. QT prolongation can lead to torsades de pointes which can progress to life-threatening ventricular fibrillation and PR prolongation may lead to complete heart block. Patients at particular risk are those with underlying heart conditions. Inform patients on this antiretroviral combination of the potential risks and counsel them concerning appropriate actions if they experience related symptoms.

Conflict Code: DD – Drug/Drug interaction
Drugs/Diseases

Util A	Util B	Util C
Saquinavir	Ritonavir	

References:
FDA: Drug Safety Communication: Invirase Labels now Contain Updated Risk Information on Abnormal Heart Rhythms. Oct. 21, 2010.

7. Tramadol Products / Therapeutic Appropriateness ___X___ _____ _____

Alert Message: Tramadol-containing products should not be prescribed for patients who are suicidal or addiction-prone. Caution should also be exercised when prescribing tramadol products to patients receiving tranquilizers, antidepressants, or patients who use alcohol in excess. Tramadol-related deaths have occurred in patients with previous histories of emotional disturbances/ suicidal ideation as well as history of misuse of tranquilizers, alcohol or CNS-active drugs.

Conflict Code: TA – Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C
Tramadol – All	Suicidal Ideation	
	Addiction	
	Drug Dependence	
	Drug Abuse	
	Alcohol Abuse	
	Tranquilizers	
	Antidepressants	
	Narcotics	

Reference:
FDA Safety MedWatch Alert, Ultram (tramadol hydrochloride), Ultracet (tramadol hydrochloride/acetaminophen): Label Changes May 25, 2010.
Ultram ER Prescribing Information, June 2009, Ortho-McNeil Janssen.
Clinical Pharmacology, 2010 Gold Standard.
Ryzolt Prescribing Information, Feb 2010, Purdue Pharma L.P.

8. Dabigatran / Overutilization ___X___ _____ _____

Alert Message: Pradaxa (Dabigatran) may be over utilized. The manufacturer's recommended maximum dose for patients with CrCl > 30mL/min is 150 mg twice daily. Exceeding the recommended daily dose may result in adverse effects including major bleeds.

Conflict Code: - ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Dabigatran		Severe Kidney Disease Stage 4 & 5

Max Dose: 300mg/day
References: Pradaxa Prescribing Information, October 2010, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

9. Dabigatran / Overutilization — X

Alert Message: Pradaxa (Dabigatran) may be over utilized. The manufacturer's recommended maximum dose for patients with CrCl 15-30 mL/min is 75 mg twice daily. Exceeding the recommended daily dose may result in adverse effects including major bleeds.

Conflict Code: - ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Dabigatran		Severe Kidney Disease Stage 4 & 5

Max Dose: 150mg/day

References:
Pradaxa Prescribing Information, October 2010, Boehringer Ingelheim Pharmaceuticals, Inc.

10. Dabigatran / Non-adherence — X

Alert Message: Non-adherence to Pradaxa (dabigatran) therapy may result in sub-therapeutic effects increasing the risk stroke and systemic embolism. If dabigatran must be temporarily discontinued for any reason, therapy should be restarted as soon as possible.

Conflict Code: LR – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Dabigatran		

References:
Pradaxa Prescribing Information, October 2010, Boehringer Ingelheim Pharmaceuticals, Inc.

11. Dabigatran / Drugs the Increase Bleeding — X

Alert Message: Pradaxa (dabigatran) increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Risk factors for bleeding include use of drugs that increase the risk of bleeding in general (e.g., antiplatelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDS) and labor and delivery. Dabigatran is contraindicated in patients with active pathological bleeding.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Dabigatran	NSAIDS	
	Aspirin	
	Heparin	
	Warfarin	
	Antiplatelet Agents	
	Fibrinolytic therapy	

References:
Pradaxa Prescribing Information, October 2010, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

12. Dabigatran / Active Bleeds X

Alert Message: Pradaxa (dabigatran) increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Dabigatran is contraindicated in patients with active pathological bleeding.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Dabigatran	GI Bleeds	
	Intracranial Hemorrhage	

References:
Pradaxa Prescribing Information, October 2010, Boehringer Ingelheim Pharmaceuticals, Inc.

13. Dabigatran / P-gp Inducers X

Alert Message: Concurrent use of Pradaxa (dabigatran) and P-gp inducers should generally be avoided. In clinical studies the co-administration of rifampin with dabigatran decrease dabigatran AUC and Cmax by 66% and 67% respectively.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Dabigatran	Rifampin	
	Carbamazepine	
	Tipranavir	
	Ritonavir	
	Dexamethasone	
	Doxorubicin	
	Nefazodone	
	Prazosin	
	Trazodone	
	Vinblastine	
Nelfinavir		

References:
Pradaxa Prescribing Information, October 2010, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2010 Gold Standard.
Hartshorn EA and Tatro DS. Principles of Drug Interactions. Facts & Comparisons E Answers. 2010 Updates.

14. Lurasidone / Overutilization X

Alert Message: Latuda (lurasidone) may be over-utilized. The manufacturer's maximum recommended dose is 80 mg once daily. Exceeding the recommended dose may increase the risk of adverse effects (e.g., akathisia, somnolence, dystonia, and parkinsonism).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Lurasidone		Moderate Renal Impairment
		Severe Renal Impairment
		Diltiazem
		Verapamil
		Aprepitant
		Fluconazole
		Erythromycin
		Chronic Liver Disease and Cirrhosis

Max Dose: 80 mg/day

References: Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

15. Lurasidone / Moderate & Severe Renal and Hepatic Impairment X

Alert Message: Latuda (lurasidone) may be over-utilized. The manufacturer's recommends that the lurasidone dose should not exceed 40 mg once daily in patients with moderate to severe renal or hepatic impairment .

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Lurasidone 80mg		Moderate Renal Impairment
		Severe Renal Impairment
		Chronic Liver Disease and Cirrhosis

Max Dose: 40 mg/day

References:
Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.

16. Lurasidone / Non-adherence X

Alert Message: Based on refill history, your patient may be under-utilizing Latuda (lurasidone). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effect, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Underutilization
Drugs/Diseases

Util A	Util B	Util C
Lurasidone		

References:
Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.

17. Lurasidone / Strong CYP3A4 Inhibitors X

Alert Message: The concurrent use of Latuda (lurasidone) with a strong CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, clarithromycin and nefazodone) is contraindicated. Coadministration of lurasidone with ketoconazole was shown to significantly increase the Cmax and AUC of lurasidone (6.9 and 9 times, respectively).

Conflict Code: DD – Drug/Drug Interactions
Drugs/Diseases

Util A	Util B	Util C
Lurasidone	Ketoconazole	Atazanavir
	Itraconazole	Saquinavir
	Indinavir	Clarithromycin
	Nelfinavir	Nefazodone
	Ritonavir	Telithromycin

References:
Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.
FDA: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

18. Lurasidone / Strong 3A4 Inducers X

Alert Message: The concurrent use of Latuda (lurasidone) with a strong CYP3A4 inducer (e.g., rifampin, carbamazepine, and phenobarbital) is contraindicated. Coadministration of lurasidone with rifampin was shown to significantly decrease the Cmax and AUC of lurasidone as compared to that of lurasidone alone ($1/7^{th}$ and $1/5^{th}$, respectively).

Conflict Code: DD – Drug/Drug Interactions
Drugs/Diseases

Util A	Util B		Util C
Lurasidone	Rifampin	Nevirapine	
	Carbamazepine	Efavirenz	
	Phenytoin		
	Rifabutin		
	Phenobarbital		
	Dexamethasone		

References:
Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

19. Lurasidone / Moderate 3A4 Inhibitors X

Alert Message: The dose of Latuda (lurasidone) should not exceed 40 mg/day when it is co-administered with a moderate CYP3A4 inhibitor (e.g., diltiazem, verapamil, aprepitant, erythromycin, fluconazole). Lurasidone is a CYP3A4 substrate and metabolic inhibition of this isozyme may result in increased lurasidone plasma concentrations and risk of adverse effects.

Conflict Code: DD – Drug/Drug Interactions
Drugs/Diseases

Util A	Util B	Util C
Lurasidone 80mg	Diltiazem	Erythromycin
	Verapamil	Fluconazole
	Aprepitant	

Max Dose: 40 mg/day
References:
Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

20. Lurasidone / Therapeutic Appropriateness — X

Alert Message: The safety and effectiveness of Latuda (lurasidone) in pediatric patients have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Lurasidone

Age Range: 0 – 17 yoa
References:
Latuda Prescribing Information, Oct. 2010, Sunovion Pharma, Inc.

21. Kapvay / Overuse — X

Alert Message: Kapvay (clonidine extended-release) may be over-utilized. The manufacturer's recommended maximum daily dose is 0.4 mg/day.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Kapvay

Age Range: 10 – 999 yoa
Max Dose: 0.4mg/day

References:
Kapvay Prescribing Information, 2010, Shionogi Pharma, Inc.

22. Kapvay / Non-adherence — X

Alert Message: Based on refill history, your patient may be underutilizing Kapvay (clonidine extended-release). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs. Also, abrupt discontinuation of clonidine may result in withdrawal effects.

Conflict Code: LR - Underutilization
Drugs/Diseases
Util A Util B Util C
Kapvay

References:
Kapvay Prescribing Information, 2010, Shionogi Pharma, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

23. Kapvay / Therapeutic Duplication — Accepted: X

Alert Message: Kapvay (clonidine extended-release) should not be used with other clonidine-containing products (e.g., Catapres, Catapres TTS, Jenloga) due to the potential for additive adverse effects (e.g., hypotension, syncope).

Conflict Code: TD - Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Kapvay	Clonidine IR	
	Clonidine Transdermal	
	Jenloga (ER for hypertension)	

References:
Kapvay Prescribing Information, 2010, Shionogi Pharma, Inc.

24. Opioids / Benzodiazepines — Approved As Amended: X

Alert Message: The co-administration of opioids and benzodiazepines should be done with caution. The concurrent use of these agents may result in respiratory depression, hypotension, profound sedation, coma **or death**. If concurrent administration is clinically warranted consider dosage reduction of one or both agents.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Methadone	Temazepam	
Meperidine	Chlordiazepoxide	
Morphine	Clorazepate	
Hydromorphone	Lorazepam	
Oxymorphone	Diazepam	
Codeine	Estazolam	
Hydrocodone	Oxazepam	
Oxycodone	Flurazepam	
Levorphanol	Alprazolam	
Fentanyl	Triazolam	
Tapentadol	Quazepam	
Tramadol	Clonazepam	

References:
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
25. Silenor / Overuse Alert Message: Silenor (doxepin) may be over-utilized. The manufacturer's recommended maximum daily dose is 6 mg, 30 minutes before bedtime. Conflict Code: ER - Overutilization Drugs/Diseases Util A Util B Util C Silenor Max Dose: 6mg/day References: Facts & Comparisons, 2010 Updates. Silenor Prescribing Information, March 2010, Somaxon Pharmaceuticals.	X		

R. Bob Mullins, Jr., M.D., Commissioner (X Approve ( ) Deny 3-18-11 Date

Kathy Hall, Deputy Commissioner (✓) Approve ( ) Deny 3/17/11 Date

Robert Moon, M.D., Medical Director (✓) Approve ( ) Deny 3-17-11 Date